DEPARTMENT OF THE ARMY
DANGER COMPANY, 54TH BRIGADE ENGINEER BATALLION
173rd INFANTRY BRIGADE COMBAT TEAM (AIRBORNE)
CASERMA DEL DIN, ITALY
APO AE 09630

AESE-BGG-D 29 September 2021

MEMORANDUM FOR RECORD

SUBJECT: Request for Food and Drug Administration (FDA) approved Vaccine for Mandatory Coronavirus Disease Vaccination

1. Attached is the Memorandum for Record from CPT Palomino [1], the Aeromedical Physician Assistant I spoke to on 27SEP21 as part of my counseling process. I do have some comments to add context to some of his statements.

2. Regarding paragraph 3a, I did not say, nor did I suggest, that the COVID-19 Vaccine was gene therapy, nor did I suggest that vaccination modifies your DNA. As I had explained, my question was out of sheer curiosity since I was unable to come to a definitive conclusion through my own research. My question was whether he could confirm that the codon optimization of the Pfizer-BioNTech COVID-19 Vaccine was the same as that in the COMIRNATY mRNA Vaccine. I said that I had read various trials of the BNT162b2 vaccine that incorporated different variants of the vaccine, with variant 9 (V9) differing from variant 8 (v8) due to the presence of optimized codons [2]. The COMIRNATY mRNA Vaccine is directly correlated to V9. During our conversation, I mentioned that I am aware that the optimization of codons touches upon gene therapy, and it is difficult to ascertain the long-term effects of products using such optimization in humans. His response was that he has not read up on the latest and great of codon optimization or corresponding nomenclature and cannot confirm whether they are the same. He added that when it comes to determining whether a vaccine is identical, from their medical perspective, it is based on the ingredients and mRNA sequencing, and they do not investigate how the codons are optimized.

3. Regarding paragraph 3c, despite the fact that the difference in labeling is significant in whether a product is considered an FDA approved product [2] and using non-FDA approved labeling violates the guidance put out by the Secretary of Defense (SECDEF) as a requirement for a mandatory vaccine [3], CPT Palomino also claimed the vaccines are identical. This is misleading as the Fact Sheet for Healthcare Providers Administering Vaccine for the Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine clearly states that the products are legally distinct with **certain differences** that do not impact safety or effectiveness [4]. If there are certain differences, it is misleading to say they are identical.

4. Regarding paragraph 4, I have several issues with the Memorandum from the Assistant Secretary of Defense [5], and I hope to utilize any professional channels possible to make sure these issues are heard and addressed. First, the sole source of the claims made in the memorandum is a page on the FDA website, not by any sort of FDA approved and/or signed document or fact sheet. Second, the document tries to cherry pick words and rearrange sentences to make statements come across as legal. Most importantly, **FDA guidance does not supersede the United States Code**. The document fails to mention that the products are **legally distinct** with certain differences [4]. The document fails to mention that the EUA for the Pfizer-BioNTech Vaccine was *reissued* two weeks before the COMIRNATY (COVID-19 Vaccine, mRNA) received FDA approval and that the Pfizer-BioNTech COVID-19 Vaccine's EUA is still active for individuals *12 and older* [4]. The document fails to mention that, as per the referenced website, *for purposes of administration*, ***doses distributed under the EUA*** are interchangeable with the licensed doses. The document suggests that the FDA stated that the vaccine *should* uses doses under the EUA while the referenced website says *can* use doses. Throughout every approval document and fact sheet, the vaccines are stated as legally distinct, and clearly state that the Pfizer-BioNTech COVID-19 Vaccine is an **unapproved product and is authorized under an EUA**, with the latest revision being a week ago today. As this product is legally distinct, this means that the Pfizer-BioNTech COVID-19 Vaccine still receives authorization from Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C), while COMIRNATY (COVID-19 Vaccine, mRNA) does not. 10 U.S.C. § 1107a specifically applies to the administration of a product authorized for emergency use under section 564 of the FD&C Act to members of the armed forces. The **Assistant Secretary of Defense does not have the authority** to waive a servicemembers right to accept or refuse an EUA vaccine. This responsibility is that of the President, and the President alone and is only waivable in writing [6]. This is an attempt to circumvent the law via wordsmithing and cherry-picking. **This memo needs to be rescinded immediately** to protect the rights of our servicemembers and to prevent coercion and wrongful punishment.

5. My final comment regarding his response is that in paragraph 2, he stated that the vaccine which they (the Vicenza Health Clinic) have on hand is the Pfizer-BioNTech COIVD-19 Vaccine and later states in paragraph 3c that these vaccines do not have the COMIRNATY label on the [vial]. This means that the order that was given in OPORD 21-029 [7] to vaccinate all Soldiers who are not otherwise exempt was designed to fail as there is no FDA approved vaccine available that meets SECDEF guidance at the Vicenza Health Clinic. Furthermore, the desired end state can be obtained only if the soldiers waive their right to refuse an EUA vaccine. **An end state or order that's success depends on the infringement of a servicemember's rights is immoral, unethical, and illegal.** This order needs to be rescinded or updated to allow for administrative waivers until Vicenza Health Clinic can receive an FDA approved vaccine that is in line with the guidance put out by the Secretary of Defense.

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6. I, again, refuse to volunteer to receive the EUA Pfizer-BioNTech Covid-19 Vaccine and instead request to receive an administrative waiver until my unit receives the FDA approved COMIRNATY (COVID-19 Vaccine, mRNA), so that I can meet the SECDEF's intent of 100% vaccination.

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Steven Brown
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Encls

1. MFR from CPT Palomino 28SEP21
2. August 23, 2021, Summary Basis for Regulatory Action - Comirnaty
3. Memorandum for Mandatory Coronavirus Disease 2019, Vaccination of Department of Defense Service Members, August 24, 2021
4. Fact Sheet for Healthcare Providers Administering Vaccine, revised 22 September 2021
5. Assistant SECDEF Memorandum for COVID-19 COMIRNATY EUA-BLA
6. 10 USC 1107a Emergency use products
7. OPORD 21-029 (173D Mandatory COVID-19 SM Vaccinations)